
From: (b) (6) </o=va/ou=exchange
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To: Leinenkugel, Jake </o=va/ou=exchange
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Cc: (b) (6) </o=va/ou=exchange
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(b) (6) f32>; (b) (6) </o=va/ou=exchange
administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6), (b) (5)
Bcc:
Subject: Briefings (not all) so you can review
Date: Wed Jul 18 2018 17:26:04 CDT
Attachments: COVER_AC (JM) FACA 101 Slides_07182018.ppt
COVER_July 2018 Patient-Centered Survey Presentation_07032018_v7.pptx
COVER_SGE Ethics Training - 2017_07182018.pptx
July 25 PPT EBR Draft Presentation 7.18.2018 wide screen ver.pptx
Whole Health and CIH Overview for July COVER Mtg_07182018.pptx

Jake – these have all been reformatted for wide screen and are ready for your review. ACMO and Ethics is the standard brief for every FACA committee/commission. Ethics is way too long and I can't believe someone has not fussed about it before now. I have a call into (b) (6) to discuss so don't freak out yet on hers. Still missing all VHA except WH which is attached.

Also have a solution for less than a quorum and will prep that for you to review and we can get the Secretary to sign that and it protects us from here on out.

Paperwork reduction: Cathy from OGC called and said to check with OIT and OMB SME and she does not see why OGC would have ever opined on it. So we will dig up those POCs and ask the same questions. She will still run it by the OGC person mentioned that will be in on Monday.

We were able to put docs on MAX today and are testing it and hope to be able to get all of you access to that before the meeting.

I also sent you the link to our internal SP so you can access that if you need to.

The additional desktop will be set up in your office tomorrow.

(b) (6) and I will pick up equipment on Friday. Table side binders will be complete Friday (assuming I get all briefings in).

Working with (b) (6) on a PD and have asked COR who brings him on - I think it has to be under OPCC since they control the budget.

Thank you

Vr/ (b) (6)

(b) (6)

Designated Federal Officer

COVER Commission

(b) (6) va.gov

202-461- (b) (6)

Owner: (b) (6) </o=va/ou=exchange administrative group (fydibohf23spdlt)
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Filename: COVER_AC (JM) FACA 101 Slides_07182018.ppt
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Federal Advisory Committee Act 101

- **What is FACA?**

- The Federal Advisory Committee Act is a Federal statute that governs the **establishment, termination and management** of Federal advisory committees (FAC). Enacted to promote openness and transparency and to regulate the number and duration of FACs.

- **When does FACA apply?**

- FACA applies to all groups with at least one non-Federal employee established or utilized by an agency to obtain advice or recommendations, unless an exception applies.

- **What are the requirements for a FAC?**

- signed/filed Charter;
- Designated Federal Officer (DFO);
- public meetings with agenda announced in Federal Register 15 days in advance and an opportunity for public to submit written comments;
- balanced membership;
- records maintained and available for public inspection.



Federal Advisory Committee Act 101

- **What constitutes a meeting?**

- FACA applies to all gatherings where substantive matters upon which the committee provides advice or recommendations are discussed.
- This includes “virtual” gatherings, such as tele- and video-conferences.

- **What is a Designated Federal Officer?**

- VA employee who manages day-to-day FAC operations;
- Must approve/call meetings, attend all meetings, and approve meeting agenda;
- Must ensure meeting minutes are certified by FAC Chair within 90 days.



Federal Advisory Committee Act 101

- **May FACs ever meet privately?**

- FACs may convene to perform two types of work without a public meeting:

- 1) Preparatory work.** A meeting convened solely to gather information, conduct research , analyze relevant issues, facts in preparation for a FAC meeting or to draft papers for deliberation by FAC;

- and**

- 2) Administrative work.** A meeting convened solely to discuss administrative matters of the FAC or receive administrative information from agency.

- FAC meetings may also be closed in whole or in part under limited circumstances, such as when discussing trade secrets, personal information, and criminal matters. OGC must concur in the closure.



Federal Advisory Committee Act 101

- **May I testify before a congressional committee or speak with congressional staff about FAC matters?**
 - If asked to testify, you may speak about FAC matters only in your personal capacity. FAC members do not have authority to testify on behalf of the FAC and do not speak for VA.
 - Your testimony should clarify that you are providing your personal opinion and are not speaking on behalf of VA or the FAC.
 - Because you are acting in your personal capacity if you testify, VA cannot not reimburse you for expenses or pay honoraria.
 - As a courtesy, we appreciate you informing the FAC's DFO if you are going to testify.

Owner: (b) (6) </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=(b) (6), (b) (5)
Filename: COVER_July 2018 Patient-Centered Survey Presentation_07032018_v7.pptx
Last Modified: Wed Jul 18 17:26:04 CDT 2018

Recommended Approaches and Considerations to Satisfy Patient- Centered Survey COVER Requirement

(b) (6)

M.D., M.P.H.

Sigma Health Consulting, LLC

July 25, 2018

COVER COMMISSION

CARA Sec. 931 – Duty 2.D – CIH Therapies

D) The experience, if any, of veterans with respect to the complementary and integrative health (CIH) treatment therapies described in paragraph (3), which include:

- 1) Music therapy;
- 2) Equine therapy;
- 3) Training and caring for service dogs;
- 4) Yoga therapy;
- 5) Acupuncture therapy
- 6) Meditation therapy;
- 7) Outdoor sports therapy;
- 8) Hyperbaric oxygen therapy;
- 9) Accelerated resolution therapy;
- 10) Art therapy
- 11) Magnetic Resonance therapy; and
- 12) Other therapies the Commission determines appropriate

Options for Gathering Patient- Centered Survey Information

Option 1: Utilize a variety of existing qualitative and quantitative data sources to satisfy one or more the Commission requirements

Option 2: Design and conduct a patient- centered web- based survey

Option 3: Combination of Option 1 and Option 2

Choosing an approach other than Option 1 will require OMB (Office of Management and Budget) approval and invoke compliance with the Paperwork Reduction Act (PRA).

All information collections subject to the PRA must be submitted to OMB for approval

See Appendix for more information on PRA, OMB approval process and timeline

Expedited OMB Review²

OMB may grant an expedited review if:

- 1) Public harm is reasonably likely to result if normal clearance procedures are followed;
- 2) An unanticipated event has occurred; or
- 3) The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed

See Appendix for more information on PRA and expedited OMB review

²44 U.S.C. § 3507(j); 5 C.F.R. 1320.13(a)(2)

COVER Commission Patient- Centered Survey: A Closer Look

Duty 2.A

Charge: Examine the experience of veterans with the Department of Veterans Affairs when seeking medical assistance for mental health issues through the health care system of the Department

Potential Data Sources

Qualitative: TBD

Quantitative: VA Survey of Healthcare Experiences of Patients (SHEP)

Gaps: Qualitative data

Solution/Approach: Gather qualitative data through townhalls or patient-centered focus groups or key-informant interviews when conducting Commission site visits

Duty 2.B

Charge: Examine the experience of veterans with non- Department facilities and health professionals for treating mental health issues

Potential Data Sources

Qualitative: TBD

Quantitative: National Academy of Medicine (NAM) study dataset given to the Northeast Program Evaluation Center (NEPEC)

Gaps: Qualitative data

Dataset from NEPEC is de- identified

Lack of CIH data

Solution/Approach: Supplement data with information collected during Commission site visits, including CIH information

Duty 2.C

Charge: Examine the preference of veterans regarding available treatment for mental health issues and which methods the veterans believe to be most effective

Potential Data Sources

Qualitative: Patient- centered focus groups for VA/DoD Clinical Practice Guidelines (CPGs)

Quantitative: VISN 6 Mental Illness Research, Education, and Clinical Center (MIRECC)

Operation Iraqi Freedom (OIF) Operation Enduring Freedom (OEF) Veterans Health and Needs Assessment Survey

Gaps: SHEP survey does not gather this data

VISN 6 MIRECC Health and Needs Assessment Survey data restricted to OIF/OEF Veterans
Veterans' preferences not well captured in standard data sources

Solution/Approach: Supplement data with information collected during Commission site visits

Identify additional quantitative data sources about other Veteran populations

Duty 2.D

Charge: Examine the experience, if any, of veterans with respect to the complementary and integrative health treatment therapies described in paragraph (3)

Potential Data Sources

Qualitative: TBD

Quantitative: Healthcare Analysis and Information Group (HAIG) survey

Gaps:

HAIG survey does not address patient experiences and may not address all of the CIH treatments listed

Solution/Approach: Supplement data with information collected during Commission site visits

Identify additional data sources that capture Veterans' patient experiences related to CIH treatments

Duty 2.E

Charge: Examine the prevalence of prescribing prescription medication among veterans seeking treatment through the health care system of the Department as remedies for addressing mental health issues

Potential Data Sources

Qualitative: Not needed for this charge

Quantitative: Corporate Data Warehouse (CDW) Pharmacy Tables or Pharmacy Benefits Management Database

Gaps: None currently identified

Solution/Approach: Analyses of existing VA pharmacological data

Duty 2.F

Charge: Examine the outreach efforts of the Secretary regarding the availability of benefits and treatments for veterans for addressing mental health issues, including by identifying ways to reduce barriers to gaps in such benefits and treatments

Potential Data Sources

Qualitative: Office of Mental Health and Suicide Prevention (OMHSP) information, Veterans Service Organizations (VSOs) information

Quantitative: TBD

Gaps: Identifying quantitative data source(s)

Solution/Approach: Can gather the number of outreach events conducted during a given time period to add quantitative analyses

Examine outreach efforts at the local and national level

Potential Challenges to Consider

If the Paperwork Reduction Act (PRA) is invoked, the OMB clearance process (takes at least 8- 12 months) may cause challenges in meeting the entire charge of the Commission within the given time frame

Any gaps or challenges in using existing data sources with meeting the entire charge of the Commission

Commission's Next Steps

Understand the existing data sources

Evaluate the gaps

Choose an approach to meet the requirements

Discussion



Appendix

CARA Sec. 931 – Duty 2

Conduct a patient- centered survey within each of the Veterans Integrated Service Networks (VISNs) to examine:

- A) The experience of veterans with the Department of Veterans Affairs when seeking medical assistance for mental health issues through the health care system of the Department;**
- B) The experience of veterans with non- Department facilities and health professionals for treating mental health issues;**
- C) The preference of veterans regarding available treatment for mental health issues and which methods the veterans believe to be most effective;**

CARA Sec. 931 – Duty 2

D) The experience, if any, of veterans with respect to the complementary and integrative health treatment therapies described in paragraph (3);

E) The prevalence of prescribing prescription medication among veterans seeking treatment through the health care system of the Department as remedies for addressing mental health issues; and

F) The outreach efforts of the Secretary regarding the availability of benefits and treatments for veterans for addressing mental health issues, including by identifying ways to reduce barriers to gaps in such benefits and treatments

Paperwork Reduction Act (PRA)¹

Created 1980; amended 1995

Provides the Office of Management and Budget (OMB) authority over the collection of certain information by Federal agencies

Goals of PRA:

Minimize the paperwork burden on the public and other entities.

Ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government.

Improve the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society.

Minimize the cost to the Federal Government of creating, collecting, maintaining, using, disseminating, and disposing of information.

Ensure the integrity, quality, and utility of the Federal statistical system.

¹Paperwork Reduction Act, P.L. 104- 13, Accessed 07032018

PRA, OMB Clearance and Surveys¹

According to PRA, surveys are considered to be information collections

Surveys may consist of many different collection instruments such as

- Web surveys

- Web exit surveys

- Focus groups

- Benefits surveys

What Information Collections require OMB clearance?

OMB must clear an information collection if the agency conducts or sponsors the collection of information from **10 or more members of the public**, regardless of whether the collection is mandatory, voluntary, or required to obtain or retain a benefit, when the information is obtained by means of identical questions or identical reporting, recordkeeping, or disclosure requirements.

¹Paperwork Reduction Act, P.L. 104- 13, Accessed 07032018

Information Collection Request (ICR) Approval Process Timeline¹

TOTAL TIME REQUIRED = up to 268 business days from beginning to end! (Over a year in calendar days)

Timeline estimate (in business days) for an ICR to undergo OPM approval and OMB approval.

- 1) Approval of 60- Day Notice via DMS. (60 days)
- 2) Publication of 60- Day Notice in the Federal Register. (4 days)
- 3) Public comment period for 60- Day Federal Register Notice. (60 days)
- 4) Approval of 30- Day Federal Register Notice via DMS. (60 days)
- 5) Publication of 30- Day Notice in the Federal Register. (4 days)

¹Paperwork Reduction Act, P.L. 104- 13, Accessed 07032018

Information Collection Request (ICR) Approval Process Timeline¹

- 6) Creation of ICR submission package in ROCIS (after 30- Day Federal Register Notice is published). (10 days)
- 7) Review and submission of ICR package to OMB. (10 days, although this varies depending on the completeness of the ICR submission package)
- 8) OMB review and passback period. The total OMB review period is 60 days, which includes the 30- day public comment period and OMB's formal 30- day review period.
OMB's formal 30- day review period does not begin until the 30- day public comment period has lapsed. (60 days)
- 9) OMB action. At the conclusion of the 60- day OMB review, OMB issues a Notice of Action (NOA) through ROCIS.
The OMB NOA contains one of three responses: Approval, Disapproval with a process for appeal, or Withdrawal.

¹Paperwork Reduction Act, P.L. 104- 13, Accessed 07032018

Expedited OMB Review³

When should an agency consider fast-track review?

When the data collection meets the following criteria:

- 1) The purpose of the collection is to assist the agency in improving existing or future service deliveries, products, or communication materials;**
- 2) Participation by respondents is voluntary;**
- 3) The collection does not impose a significant burden on respondents;**
- 4) The collection does not require statistical rigor in order to have practical utility for improving existing or future service deliveries, products, or communication materials; and**
- 5) Public dissemination of results is not intended**

³FAQs for New Fast-Track Process for Collecting Service Delivery Feedback under PRA (Jan 30 2012)_Accessed 07162018

Expedited OMB Review³

What kinds of activities are covered under the fast-track review?

Examples include:

Comment cards or complaint forms;

Focus groups;

One-time or panel discussion groups;

Moderated, un-moderated, in-person, and/or remote-usability studies;

Testing of a survey or other collection to refine questions;

Post-transaction customer surveys (e.g., by call centers)

On-line surveys; and

Customer satisfaction qualitative surveys (e.g., those designed to detect early warning signs of dissatisfaction with agency service delivery)

³FAQs for New Fast-Track Process for Collecting Service Delivery Feedback under PRA (Jan 30 2012)_Accessed 07162018

Expedited OMB Review³

What kinds of collections are generally not eligible for fast-track?

Examples include:

Surveys that require statistical rigor because they will be used for making significant policy or resource allocation decisions;

Collections whose results are intended to be published;

Collections that impose significant burden on respondents or significant costs on the Government;

Collections that are on potentially controversial topics or that raise issues of significant concern to other agencies;

Collections that are intended for the purpose of basic research and that do not directly benefit the agency's customer service delivery; and

Collections that will be used for program evaluation and performance measurement purposes

³FAQs for New Fast- Track Process for Collecting Service Delivery Feedback under PRA (Jan 30 2012)_Accessed 07162018

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Ethics Training for Special Government Employees





Who is an SGE?

Advisory Committee members appointed to serve not more than 130 days during any 365-day period (with or without compensation)

Assume here that Committee members will serve less than 60 days in any 365-day period

Not an SGE if you serve on Committee as representative of an outside organization or another Federal agency.

2/22/2019



How to Get Ethics Advice

Contact an ethics official on OGC's Ethics Specialty Team:

- Telephone: (202) 461-6000 or
202-461-7694 – EST Central Office main number
- E –Mail: GovernmentEthics@va.gov

2/22/2019



Why Get Advice?

Seeking advice from an ethics official in advance of taking action and complying with that advice will, in virtually all cases, protect an SGE from criminal prosecution or other administrative action

Good idea to get advice in writing

2/22/2019



When do the Ethics Rules Apply?

Ethics rules apply even if SGE serves without compensation

Ethics rules apply even on days when SGE is not directly performing Government services

SGEs are Government employees for ethics purposes, but are subject to less restrictive conflict of interest requirements and ethics rules

2/22/2019



Financial Disclosure

Unless exempted by written DAEO determination – all SGE Advisory Committee members must submit Confidential Financial Disclosures

Regular Government Employee members of Advisory Committees should submit reports as well (if already a filer – a copy of most recent OGE 450 or SF 278 is acceptable)

Report must be certified before SGE can participate in any deliberative meeting

2/22/2019



Categories of Ethics Laws

Criminal conflict of interest statutes; 18 U.S.C. §§ 201-209

Standards of Ethical Conduct for Executive Branch Employees; 5 C.F.R. part 2635

Other, Constitution, Hatch Act . . .

2/22/2019



Conflicts of Interest

18 U.S.C. § 208

It is a crime for you to participate personally and substantially as a Government officer or employee in a particular matter which will directly and predictably affect your financial interest or a financial interest imputed to you.

2/22/2019



Persons whose Financial Interests are Imputed to You

Spouse

Minor Child

General Partner

Organization in which SGE serves as officer, director, trustee, general partner, or employee

Person or organization with which SGE is negotiating with, or has, arrangement concerning prospective employment

2/22/2019



Defining “Particular Matter”

Deliberations, decisions, actions focused on interests of:

- specific parties (e.g., a contract, grant, or case in litigation)

OR

- general applicability (focused on a discrete and identifiable class such as an industry)

NOT broad policy directed at large and diverse group

2/22/2019



“Direct and Predictable Effect”

Yes: Close causal link between decision or action to be taken and any effect of the matter on the financial interest

No: Link between financial interest and effect of matter is attenuated or effect is contingent upon occurrence of events that are speculative or independent of the matter

2/22/2019



Exception for Particular Matter of General Applicability

SGEs **may** participate in particular matters of general applicability where the disqualifying financial interest arises from the SGE's non-Federal employment or prospective employment

ONLY where there is no “special or distinct effect” on SGE or the non-Federal employer other than as part of a class

Exception does not cover interests arising from stock ownership

Non-Federal employment must involve actual employer/employee relationship (not contractor)

2/22/2019



Other Exceptions

Individual Waiver (in writing)

- Need for SGE services outweighs potential for conflict
- Waiver issued by appointing official

Multi-campus Exception

- Can participate in matter affecting one campus of multi-campus State institution of higher education where disqualifying interest arises from employment with separate campus of the same institution; no multi-campus responsibilities

2/22/2019



Appearances Matter

Standard of conduct issue, not criminal, but analysis similar to criminal conflict of interest law

SGE/employee cannot participate in specific party matter where a person with whom you have a “covered relationship” is, or represents, a party

2/22/2019



Appearances Matter

You have a “covered relationship” with all persons whose interests are yours under criminal conflict law, plus others

Bottom line-would a reasonable person with knowledge of all the relevant facts question your impartiality in the matter?

2/22/2019



Prohibited Compensation

For regular Federal employees - No non-Federal compensation for performance of official duties, except from treasury of State, local, municipal government. 18 U.S.C. § 209.

— N/A to SGEs

For all employees -- No \$ to be influenced to perform your duties.
18 U.S.C. § 201

2/22/2019



Switching Sides

SGE is prohibited from receiving compensation based on their representation or anyone else's before any Federal agency or court in connection with any specific party matter in which they participated personally and substantially as a Government employee. 18 U.S.C. § 203.

SGE is prohibited from acting as agent or attorney, with or without compensation before any Federal agency or court in connection with any specific party matter in which they participated personally and substantially as a Federal employee. 18 U.S.C. § 205.

2/22/2019



Switching Sides

Post-Government employment concept of no side switching.
18 U.S.C. § 207.

Lifetime Ban – representing back to the Government in connection with particular matter involving specific parties in which SGE participated personally and substantially (“behind the scenes” advice OK)

2/22/2019



Side Switching

Related Standard of Conduct prohibition

SGE may not serve as an expert witness for party opposing the Government where SGE participated in the underlying proceedings as a Government employee

SGE may not serve as an expert for party opposing their own agency where they serve on a committee established by statute or serve for more than 60 days

2/22/2019



Standards of Conduct

“Public Service is a public trust”

14 Principles boil down to two main prohibitions:

- Do Not **Use Your Public Office for Private Gain**
- Do Not **Give Unauthorized Preferential Treatment** to Any Private Organization or Individual

2/22/2019



Misuse of Position

No use of non-public information to engage in any financial transaction or to further own private interest or that of another

No use of Government property for other than authorized purposes

No use/allowing use of official title, position or authority to imply that the Department officially endorses/sanctions a private product, service or activity

2/22/2019



Teaching, Speaking, and Writing

No compensation for Teaching, Speaking, or Writing that relates to official duties

Relates to Official Duties if:

- Undertaken as part of official duties,
- Invitation extended primarily because of official position,
- Invitation from someone whose interests may be substantially affected by member's Government duties,
- Information conveyed draws substantially on non-public information, or
- Subject matter deals significantly with any specific party matter to which SGE is assigned or was assigned within past year of current SGE appointment

2/22/2019



Teaching, Speaking and Writing

Exception – Teaching a course requiring multiple presentations offered as part of regular curriculum of an elementary/high school or institution of higher education or training program sponsored by the Federal Government.

2/22/2019



Gifts

May not accept gift given because of official position OR from a “prohibited source”

Prohibited Source:

- Entity seeking official action by VA
- Entity doing/seeking business with VA
- Entity could be substantially affected by Committee decisions
- Entity of which a majority of members are prohibited sources

2/22/2019



Gifts

Exception – MAY accept meals, lodgings, transportation and other benefits arising from outside employment when benefits not offered due to status as Federal employee.

Other minor exceptions exist, e.g., de minimis \$20 per occasion, \$50 during calendar year – consult an ethics official.

2/22/2019



Charitable Fundraising

SGE may engage in fundraising in a personal capacity as long as SGE does not personally solicit funds or support from a person whose interests may be substantially affected by the performance or nonperformance of the SGE's official duties

2/22/2019



Other Laws and Regulations

Emoluments Clause

- Prohibits employment with, receipt of gifts decoration or titles of nobility from a foreign government or public university or commercial enterprise owned or operated by a foreign government, except to extent authorized by Congress. U.S. Constitution, Art. 1 § 9, cl.8

Foreign Gifts and Decorations Act

- No gifts > \$375 from foreign government or international organization (includes travel unless takes place entirely outside U.S.)

Foreign Agents

- No acting as agent of a foreign principal registered under Foreign Agents Registration Act unless deemed in national interest by head of agency where SGE employed



Hatch Act

Restricts certain political activities of Government employees

Applies to SGEs only when engaged in Government business:

- No political activity on duty, on Government property, or while using a Government vehicle
- No soliciting/receiving political contributions
- May be candidate for public office in partisan elections – but no campaign work while on duty

2/22/2019



Where to Get Ethics Advice?

VA Ethics Officials: GovernmentEthics@va.gov

Tammy Kennedy, Chief Counsel

Designated Agency Ethics Official (DAEO)

VACO Deputy Ethics Officials:

(b) (6)

(b) (6)

(b) (6)

(b) (6)

Office of General Counsel (023)

810 Vermont Avenue, NW

Washington, DC 20420

(202) 461-7694 or (202) 461-6000



Where to Get Ethics Advice?

Outside VACO:

OGCNorthEastEthics@va.gov for ME, NH, VT, MA, RI, CT, NY, NJ, DE, PA, OH, WV, MI, WI

OGCSouthEastEthics@va.gov for VA, NC, SC, GA, FL, MS, AL, LA, southern TX, Puerto Rico

OGCMidwestEthics@va.gov for DC, MD, IN, KY, TN, AR, MO, IL, IA, MN, ND, SD, NE, KS,

OGCWestEthics@va.gov for northern TX, OK, NM, AZ, CO, UT, WY, MT, ID, NV, CA, OR, WA, HI, AK, Guam, Philippines



Questions?



2/22/2019

Owner: (b) (6) </o=va/ou=exchange administrative group (fydibohf23spdlt)
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Recommended Approach for an Evidence- Based Review on the Effectiveness of Complementary and Integrative Health (CIH) Treatments for Mental Health Disorders

(b) (6)

[REDACTED] M.D., M.P.H.

Sigma Health Consulting, LLC

July 25, 2018

COVER COMMISSION

Aims of this session...

Review Comprehensive Addiction Recovery Act (CARA) Commission charge related to conducting an evidence-based review

Describe proposed evidence-based review timeline

Provide introduction to evidence-based reviews

Discuss scope of COVER Commission's evidence-based review and key questions

Comprehensive Addiction Recovery Act (CARA) [P.L. 114- 198]

SEC. 931. EXPANSION OF RESEARCH AND EDUCATION ON AND DELIVERY OF COMPLEMENTARY AND INTEGRATIVE HEALTH TO VETERANS.

Subparagraph (b)(3):

“Examine available research on complementary and integrative health treatment therapies for mental health issues and identify what benefits could be made with the inclusion of such treatments for veterans, including with respect to –

- A. Music therapy;
- B. Equine therapy;
- C. Training and caring for service dogs;
- D. Yoga therapy;
- E. Acupuncture therapy;
- F. Meditation therapy;
- G. Outdoor sports therapy;
- H. Hyperbaric oxygen therapy;
- I. Accelerated resolution therapy;
- J. Art therapy;
- K. Magnetic resonance therapy; and
- L. Other therapies the Commission determines appropriate”.

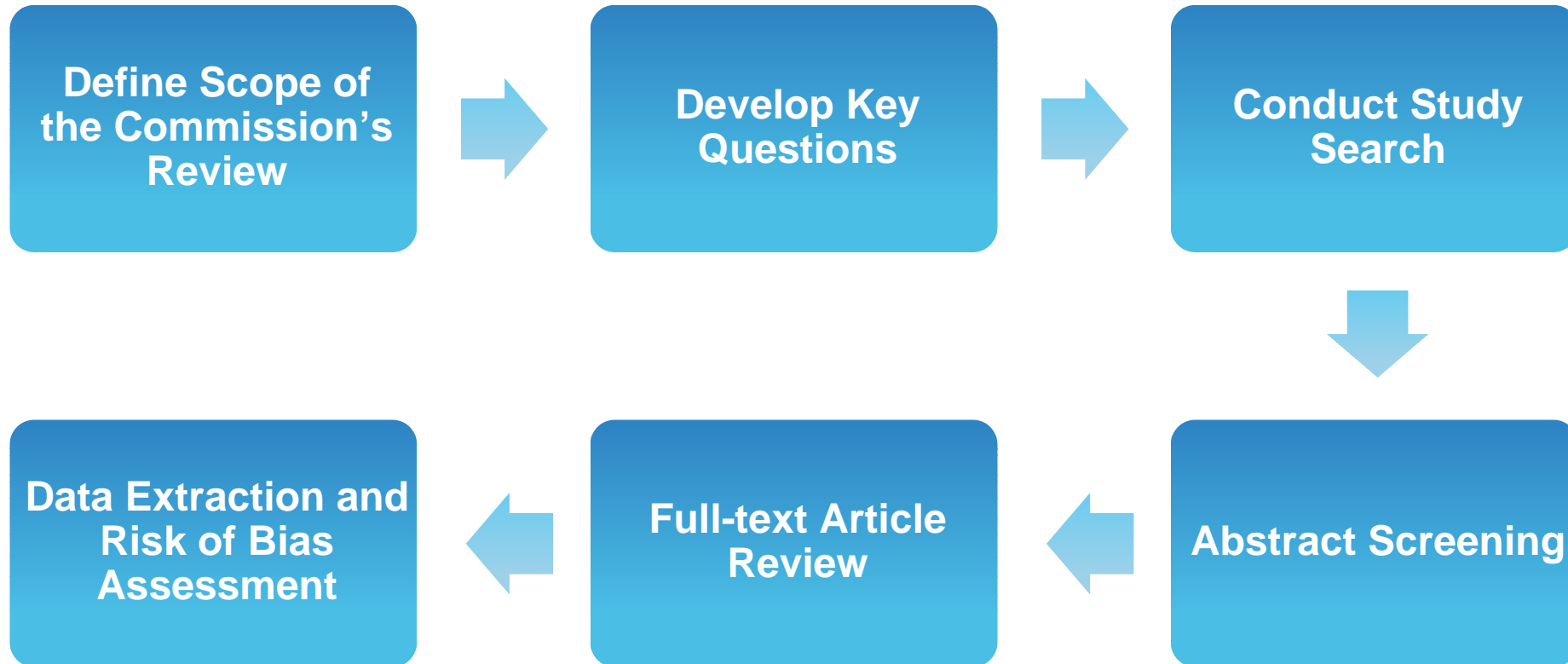
Proposed Timeline for Conducting Evidence-Based Review

Tasks	2018												2019											
	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Protocol preparation (scope, KQs, PICOTS)																								
Commissioners approve key questions at July 24-25 meeting																								
Search for studies																								
Title/abstract screening																								
Screen full- text studies																								
Design data extraction form(s)																								
Critical appraisal																								
Data extraction																								
Synthesize results																								
Discuss findings																								
Report/recommendations write- up																								

One Component of Sigma's Proposed Approach: Conduct an Evidence-Based Review

What is the purpose of an evidence-based review?

Evidence- Based Review Steps



COVER Evidence- Based Review Proposed Scope: Population

Adults 18 years or older with:

Post- Traumatic Stress Disorder (PTSD)

Major Depressive Disorder (MDD)

Substance Use Disorder (SUD)

Alcohol Use Disorder (AUD)

Opioid Use Disorder (OUD)

Suicidal Behavior

Define Evidence- Based Review Questions

Well- formulated questions guide review process

A clear, concise statement of review's objectives
(or questions) is critical

PICO(TS) will help us accomplish this

What are PICO(TS)*?

Questions Defining the Evidence- Based Review

Population

Intervention

Comparator

Outcome

Timing

Setting(s)

COVER Evidence- Based Review Proposed Scope: Comparators

Key Questions

Each mental health condition will be addressed by three key questions:

1. Are complementary and integrative health (CIH) treatments effective as **monotherapy** for improving mental health outcomes?
2. Are CIH treatments effective as an **adjunct to pharmacotherapy** for improving mental health outcomes?
3. Are CIH treatments effective as an **adjunct to psychotherapy/psychosocial interventions** for improving mental health outcomes?

Example PICO(TS) Table: Post-Traumatic Stress Disorder (PTSD)

<u>Population</u>	<u>Intervention</u>	<u>Comparator</u>	<u>Outcome</u>	<u>Timing</u>	<u>Setting(s)</u>
Adults 18 years or older with PTSD diagnosis	Complementary and Integrative Health treatments (CIH): <ul style="list-style-type: none"> • Music therapy • Equine therapy • Training/caring for service dogs • Yoga/Tai Chi therapy • Acupuncture therapy • Meditation/ Mindfulness therapy • Outdoor sports therapy • Hyperbaric oxygen therapy • Accelerated resolution therapy • Art therapy • Magnetic resonance therapy 	Usual care or placebo	<ul style="list-style-type: none"> • Improvement in global PTSD severity • Adverse events • Loss of diagnosis/remission • Self-reported PTSD symptom improvement • Comorbid symptoms • Quality of life • Functional status • Patient satisfaction 	At least 60-day follow-up	<ul style="list-style-type: none"> • Primary care • Specialty care • Mental health care

COVER Evidence- Based Review Proposed Scope: Interventions

Complementary & Integrative Health (CIH) Treatments

Music therapy;

Equine therapy;

Training and caring for service dogs;

Yoga and Tai Chi therapy;

Acupuncture therapy;

Meditation and Mindfulness;

Outdoor sports therapy;

Hyperbaric oxygen therapy;

Accelerated resolution therapy;

Art therapy;

Magnetic resonance therapy

Pharmacotherapy treatments

Psychotherapy/Psychosocial treatments

COVER Evidence- Based Review Proposed Comparison(s)

PTSD	MDD	AUD	ODU	Suicidal Behavior
Pharmacotherapy treatments				
SSRIs <ul style="list-style-type: none">SertralineParoxetineFluoxetine SNRIs <ul style="list-style-type: none">Venlafaxine TCAs <ul style="list-style-type: none">Imipramine MAOIs <ul style="list-style-type: none">Phenelzine Other antidepressants <ul style="list-style-type: none">Nefazodone Ketamine	SSRIs <ul style="list-style-type: none">FluoxetineParoxetineEscitalopramCitalopramVolazodoneVortioxetine SNRIs <ul style="list-style-type: none">DuloxetineVenlafaxineLevomilnacipramDesvenlafaxine Tetracyclic antidepressant <ul style="list-style-type: none">Mirtazapine NDRI <ul style="list-style-type: none">Bupropion Ketamine	Acamprosate Disulfiram Naltrexone Topiramate Ketamine	Buprenorphine/ Naloxone Methadone Ketamine	Lithium Ketamine
Psychotherapy/Psychosocial treatments				
Prolonged Exposure CPT EMDR Trauma- focused CBT BEP NET Written NET Stress Inoculation Present- Centered IPT	Acceptance and Commitment Behavioral therapy/ Behavioral activation CBT Computer- based CBT IPT Mindfulness- based Cognitive therapy Problem Solving Therapy	Behavioral couples therapy CBT Community reinforcement Motivational enhancement 12- Step facilitation	CBT Motivational enhancement Combined CBT/ Motivational enhancement	Cognitive therapy Problem Solving Therapy

COVER Evidence-Based Review Proposed Outcome(s)

PTSD	MDD	AUD	OOD	Suicidal Behavior
<ul style="list-style-type: none"> • Improvement on global PTSD severity • Adverse events • Loss of diagnosis/remission • Self-reported PTSD symptom improvement • Comorbid symptoms • Quality of life • Functional status • Patient satisfaction 	<ul style="list-style-type: none"> • Improvement in global MDD severity • Adverse events • Loss of diagnosis/remission • Self-reported MDD symptom improvement • Comorbid symptoms • Quality of life • Functional status • Patient satisfaction 	<ul style="list-style-type: none"> • Return to any heavy drinking • Drinking days • Heavy drinking days • Drinks per day • Time to relapse • Relapse • Percent of heavy drinking days • Adherence with treatment or abstinence • Morbidity • Mortality • Quality of life 	<ul style="list-style-type: none"> • Time to relapse • Relapse • Adherence with treatment or abstinence • Retention/ engagement in treatment program • Number lost to treatment • Duration of involvement in treatment • Adverse events • Morbidity • Mortality • Overdoses • Quality of life 	<ul style="list-style-type: none"> • Suicide attempts • Suicide deaths • Suicide ideation • Quality of life • Overdose • Readmissions • Health status • Symptomology

Questions and Discussion



COVER COMMISSION

Appendix

One Component of Sigma's Proposed Approach: Conduct an Evidence- Based Review

What is the purpose of an evidence- based review?

To **conduct** a rigorous (unbiased), comprehensive, transparent, reproducible review of relevant evidence for a clinical or policy question

To **identify** the “best evidence” for health- related decision making (in healthcare, policy, guidelines)

To **summarize** the strength and limitations of the evidence for decision- making

To **identify** important research gaps inhibiting evidence- based decisions

Define Evidence- Based Review Questions

Well- formulated questions guide many aspects of review process

- Search strategy

- Inclusion/exclusion criteria

- Presentation/dissemination of findings

A clear, concise statement of a review's objectives
(or questions) is critical and should include:

- Interventions to be reviewed

- Targeted problem

PICO(TS) will help us accomplish this

What are PICO(TS)*?

Questions Defining the Evidence- Based Review

Population. What patient(s) are of interest? Includes the condition(s), populations or sub- populations, disease severity or stage, co- morbidities, and other patient characteristics or demographics.

Intervention. What treatment or intervention will be provided for the patient?

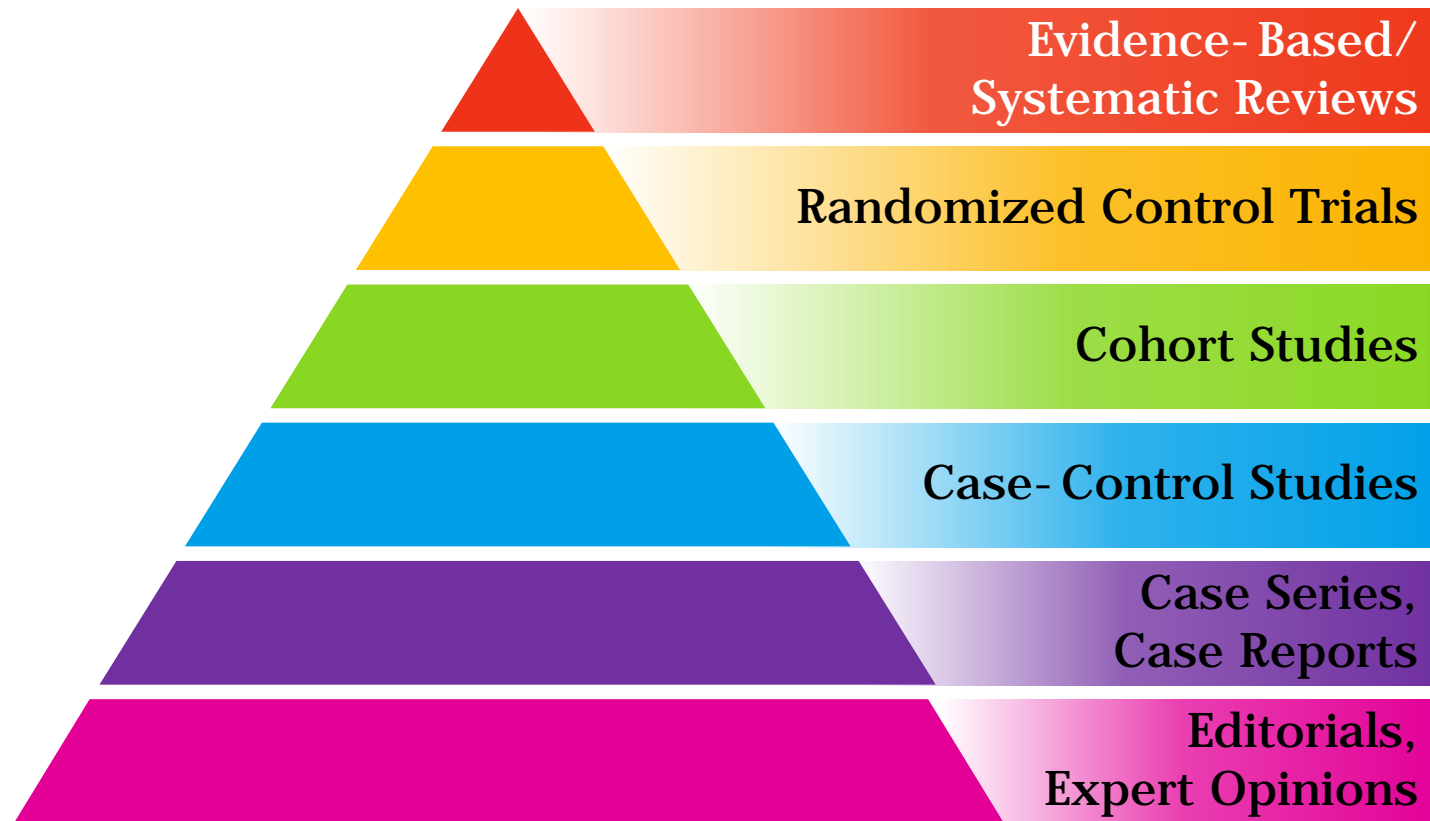
Comparator. What are the alternative treatments that will be used as a comparison? Describes what is being compared with the chosen intervention e.g. placebo, medications, psychotherapy, etc.

Outcome. How will success be measured? Describes what will be improved such as such as morbidity, mortality, quality of life, adverse events, etc.

Timing. Describes the duration of time that is of interest for the particular patient outcome, benefit, or harm to occur. (*if applicable)

Setting(s). Where do the interventions take place (e.g. primary care, specialty care)? (*if applicable)

Hierarchy of Evidence



Owner: (b) (6) </o=va/ou=exchange administrative group (fydibohf23spdlt)
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Filename: Whole Health and CIH Overview for July COVER Mtg_07182018.pptx
Last Modified: Wed Jul 18 17:26:04 CDT 2018



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Cultural Transformation

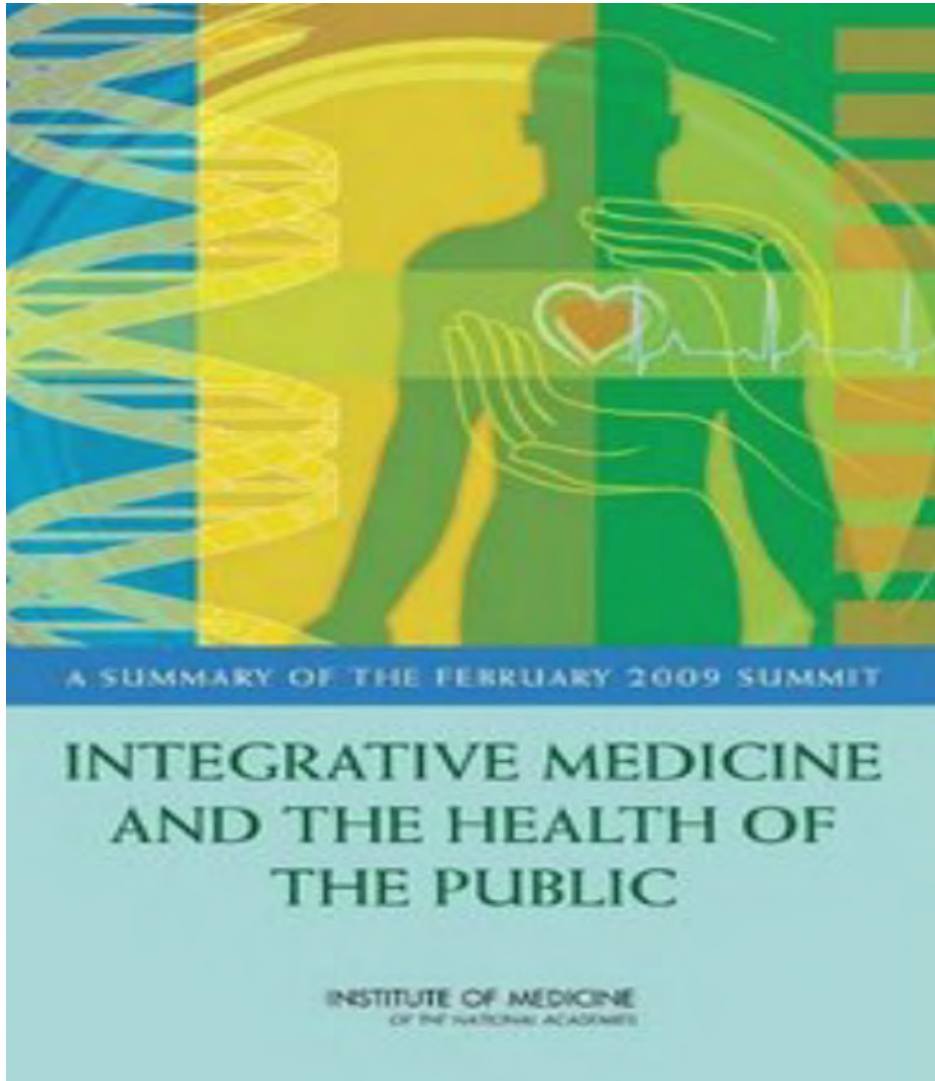


Whole Health Practices: Education, Research, and CIH Approaches

Presentation for: COVER Commission

Presented by: (b) (6) MD, (b) (6) MD & (b) (6) MPH, RYT,
PMP Office of Patient Centered Care and Cultural Transformation

Date of Briefing: July 24, 2018

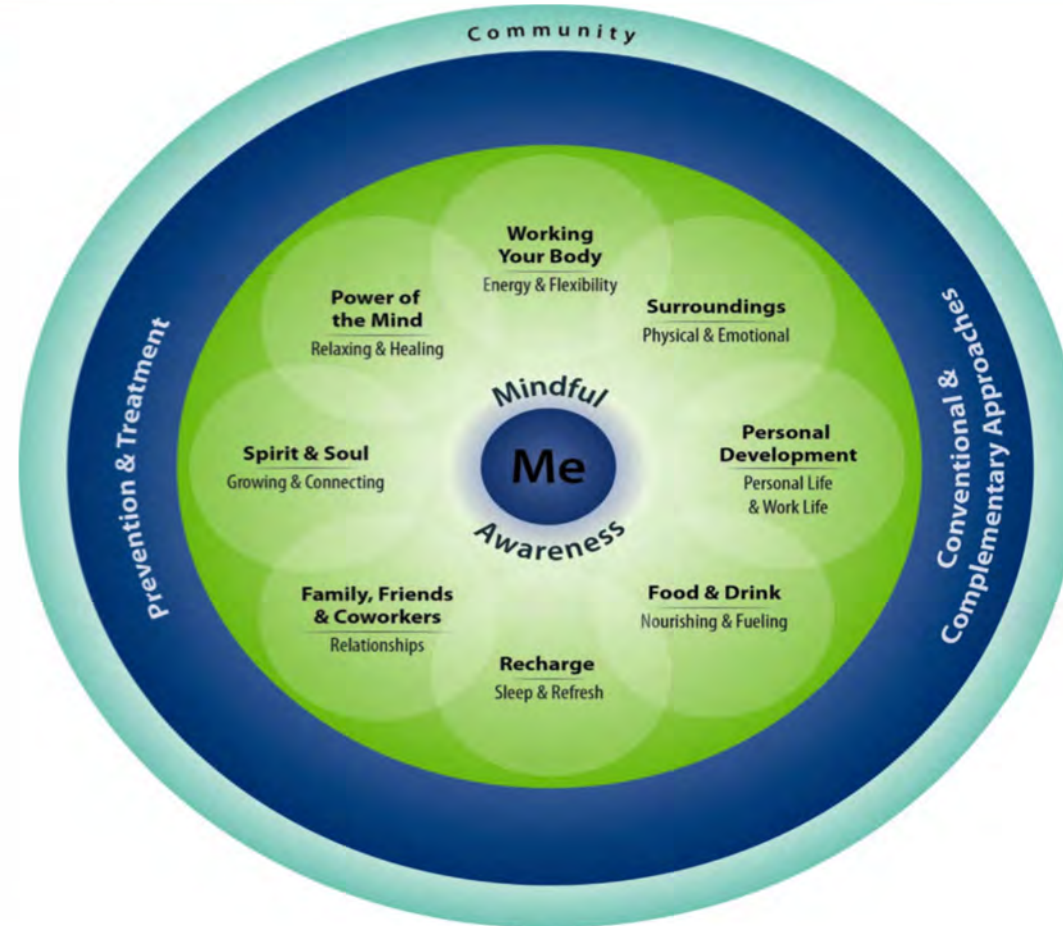


“The disease-driven approach to care has resulted in spiraling costs as well as a fragmented health system that is reactive and episodic as well as inefficient and impersonal.”

The Institute of Medicine
Summit on Integrative Medicine and
the Health of the Public, Feb 2009

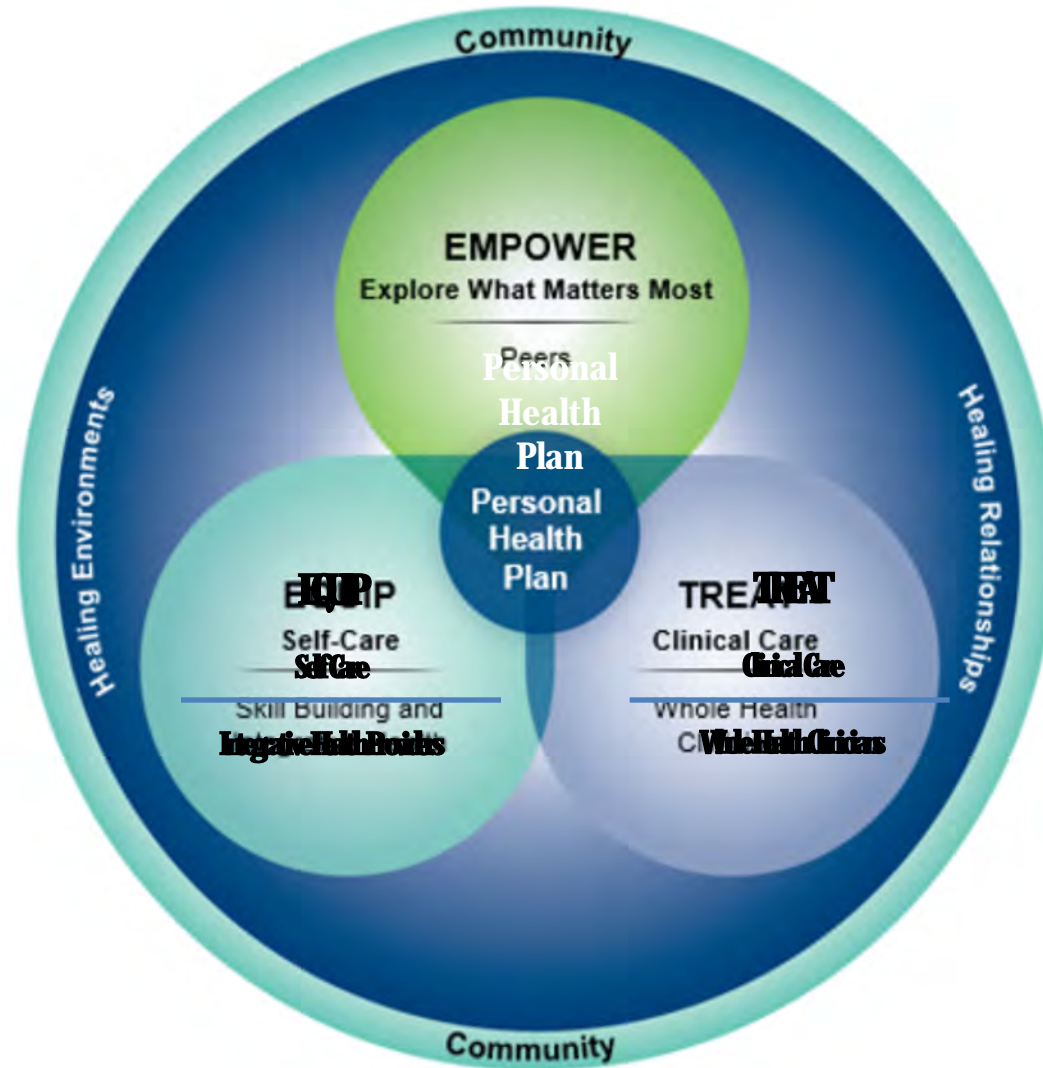


The Whole Health Approach





The Whole Health System





Education



Current Practice (FY 18)

- 71 National Educational Offerings
- 58 Offerings at Flagship Sites
 - 3500 employees trained
 - 36 Flagship Site Education Champions trained

Planned Practice (FY 19)

- 119 National Educational Offerings
- 46 Offerings at Flagship sites
- New Initiative for Whole Health for Mental Health

Gaps: More facility level training needed for large employee population/site

Recommendations: Offer train the trainer courses to meet demand, offer national VA training for delivery of CIH approaches (example BFA)



Research

Current Practice

- \$81 million DoD/VA/NIH collaborative to study CIH in pain management; 7 studies in VA
- VA Health Services Research & Development (HSR&D) study on active versus passive approaches
- Mantram repetition for PTSD
- State of the Art (SOTA) meeting in 2016- non-pharm approaches to pain; recommendations published in Journal of Internal Medicine
- VA Evidence-based Synthesis Program (ESP) reports on acupuncture, tai chi, yoga, mindfulness, massage
- Virtual CIH summit: 60+ researchers over 2 days discussed CIH for pain, MH, and well-being; recommendations shared with VA Office of Research and Development (ORD)

Planned Practice

- ESP reports for clinical hypnosis, biofeedback, guided imagery
- Strong collaboration between VA ORD/HSR&D and Office of Pain Management, and working towards even stronger collaboration for research in mental health and CIH
- Evaluating Patient Centered Care (EPCC) flagship evaluation research to look at patients with chronic pain and evaluated MH, QOL outcomes (10,000 Veterans)

Gaps: Although strong collaboration with mental health, increased research in this area can be helpful for further integration of CIH into conventional care

Recommendations: Continue to foster research collaborations with mental health



CIH Approaches



Current Practice

- List of CIH approaches part of medical benefits package per VHA Directive 1137
- Business infrastructure put in place to track these approaches, including innovative coding system (CHAR 4, CPT's, stop codes, note titles, health factors)
- SME's assembled to help in implementation of each approach
- VISN infrastructure for WH includes network sponsors and CIH POC's

Planned Practice

- Continued growth of each of the list I CIH approaches due to supporting evidence
- Support field with new qualification standards and recommended minimum proficiencies and Standard Episodes of Care (SEOC's) for community care providers
- Strengthening community partnerships for Whole Health resources for Veterans
- Reinforcing that CIH is a part of a whole health system of care and personal health planning

Gaps: Consistent use of new CIH and Whole Health coding and tracking infrastructure

Recommendations: Align resources to support VISNs and local medical facilities to ensure appropriate delivery and tracking of CIH approaches



Whole Health System Flagships



Current Practice

- 18 Flagship sites launched Oct 2017
- Whole Health System of care as a vehicle for delivering CIH in conventional care
- Learning Collaboratives – Institute for Healthcare Improvement (IHI) model
- EPCC evaluation strategy for QOL, pain, MH, and employee well-being
- EPCC implementation evaluation strategy

Planned Practice

- Full scale deployment over 3 years, touching 30% of unique Veterans/flagship facility
- Transform whole health clinical care to allow for personal health planning for each Veteran
- Target Opioid use disorder patients, chronic pain patients, and mental health patients
- Support spread of Whole Health through VISN facilities
- Growth of CIH approaches being offered to Veterans per Directive 1137

Gaps/Risks: We fail to see this as a large system transformation.

Recommendations: We must align resources and measurements with desired outcomes. Develop measures of life-long health and well-being. This requires commitment to the Whole Health System transformation from all levels of VA leadership.

Recent Coverage

- Columbia, MO: [More than Medicine: Veteran's Hospital Takes Wellness Approach to Combat Veteran Health Problems](#)
- Tomah, WI: [Tomah VA Whole Health Program Gives Options to Veterans](#)
- Tampa, FL: [VA, YMCA Team Up to Boost Veterans' Health](#)
- Clarksburg, WV: [Staff, Patients Embrace Whole Health Initiative at Clarksburg V.A.](#)
- Iron Mountain, MI: [VA Hospital, associated clinics offering holistic approach to care](#)
- Insider VA: [VA Uses Whole Health to Prevent Veteran Suicide](#)
- West LA: [Warrior pose: On the front lines of the VA's wellness transformation](#)
- Boston, MA: [VA turns to alternative pain treatments amid opioid crisis](#)
- Invited presentation to the Giving Pledge, participants included Bill Gates, Warren Buffet, and Richard Branson



Veterans committed their lives, health,
and well-being to Mission Success in
defense of our country.

Now, we can help them be mission ready for their lives, optimizing their health in service of what matters to them.

How Will We Identify Success?
When Veterans achieve outcomes they never even imagined



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**And oh,
by the way,
clinical outcomes improve
and costs decrease.**